

Please type a sign (+) inside this box



PTO/SB/05 (08-00)
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR § 1.53(b))

Attorney Docket No. 0609.4820002/SRL/TBB
First Inventor Thomas J. Gardella et al.
Title Polypeptide Derivatives of Parathyroid Hormone (PTH)
Express Mail Label No.

10/19/00
10/19/00
10/19/00



APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO:

Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original, and a duplicate for fee processing)
2. ☐ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 82]
(preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 8]
12
5. Oath or Declaration [Total Pages 12]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed)
 - i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR §§ 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76.

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program
(Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
 - a. ☒ Computer Readable Form (CRF)
 - b. Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☒ paper
 - c. ☒ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☒ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement (when there is an assignee) ☐ Power of Attorney
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☒ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☒ Other: Authorization under 37 C.F.R. § 1.136(a)(3) (in duplicate)
☒ Other: Letter to PTO Draftsman: Submission of Formal Drawings w/13 sheets Formal Drawings

17. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-Part (CIP)
Prior application information: Examiner

of prior application No: /
Group/Art Unit:

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label

(Insert Customer No. or Attach bar code label here)

or ☒ Correspondence address below

NAME	STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.				
	Attorneys at Law				
ADDRESS	Suite 600, 1100 New York Avenue, N.W.				
CITY	Washington	STATE	DC	ZIP CODE	20005-3934
COUNTRY	USA	TELEPHONE	(202) 371-2600	FAX	(202) 371-2540

NAME (Print/Type)	Steven R. Ludwig	Registration No. (Attorney/Agent)	36,203
SIGNATURE		Date	September 29, 2000

Burden Hour Statement: this form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

SKGF Rev 9/19/00 mac 4822appfnn

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid control number.

**FEE TRANSMITTAL
for FY 2000**

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT

(\$)**2,946****Complete if Known**

Application Number	(to be assigned)
Filing Date	(herewith)
First Named Inventor	Thomas J. Gardella et al.
Examiner Name	(to be assigned)
Group Art Unit	(to be assigned)
Attorney Docket No.	0609.4820002/SRL/TBB

METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayment to:

Deposit Account Number

19-0036

Deposit Account Name

Sterne, Kessler, Goldstein & Fox P.L.L.C.

- ☐ Charge Any Additional Fee Required Under 37 CFR §§ 1.16 and 1.17

- ☐ Applicant claims small entity status See 37 CFR 1.27

2. ☒ Payment Enclosed:

- ☒ Check ☐ Credit card ☐ Money Order ☒ Other*

*Charge any deficiencies or credit any overpayments in the fees or fee calculations of Parts 1, 2 and 3 below to Deposit Account No. 19-0036.

FEE CALCULATION**BASIC FILING FEE**

Large Fee Code	Large Fee (\$)	Small Fee Code	Small Fee (\$)	Fee Description	Fee Paid
101	690	201	345	Utility filing fee	690
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	334	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) (\$)**690****2. EXTRA CLAIM FEES**

	Extra	Fee from below	Fee Paid
Total Claims <u>107</u> - 20** = <u>87</u>	X	<u>18</u>	= <u>1566</u>
Indep. Claims <u>8</u> - 3** = <u>5</u>	X	<u>78</u>	= <u>390</u>
Multiple Dependent		<u>260</u>	= <u>260</u>

** or number previously paid, if greater; For Reissues, see below

Large Fee Code	Large Fee (\$)	Small Fee Code	Small Fee (\$)	Fee Description
103	18	203	9	Claims in excess of 20
102	78	202	39	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim
108	78	209	39	**Reissue independent claims over original patent
110	18	210	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)**2216****FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for <i>es parte</i> reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	380	216	190	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,360	218	680	Extension for reply within fourth month	
128	1,850	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,210	241	605	Petition to revive - unintentional	
142	1,210	242	605	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	481	40	Recording each patent assignment per property (times number of properties)	40
146	690	246	345	Filing a submission after final rejection (37 CFR 1.129(a))	
149	690	249	345	For each additional invention to be examined (37 CFR 1.129(b))	
179	690	279	345	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) :

Other fee (specify) :

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)**40****SUBMITTED BY****Complete (if applicable)**

Name (Print/Type)	Steven R. Ludwig	Registration No. (Attorney/Agent)	36,203	Telephone	202-371-2600
Signature		Date	09/29/00		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PHONE: (202) 371-2600 FACSIMILE: (202) 371-2540

KAREN R. MARKOWICZ**
SUZANNE E. ZISKA**
BRIAN J. DEL BUONO**
ANDREA J. KAMAGE**
NANCY J. LEITH**
TARJA H. NAUKKARINEN**

*BAR OTHER THAN D.C.
**REGISTERED PATENT AGENTS

sludwig@skgf.com

Thomas J. Gardella
Henry M. Kronenberg
John T. Potts, Jr.
Harald Jüppner

511 U.S. PTO
09/672020

09/29/00

09/29/00

U.S. PTO
690 U.S.

1. **Introduction**
 2. **Background**
 3. **Methodology**
 4. **Results**
 5. **Discussion**
 6. **Conclusion**
 7. **References**
 8. **Appendix**
 9. **Index**
 10. **Table of Contents**
 11. **Figure 1**
 12. **Figure 2**
 13. **Figure 3**
 14. **Figure 4**
 15. **Figure 5**
 16. **Figure 6**
 17. **Figure 7**
 18. **Figure 8**
 19. **Figure 9**
 20. **Figure 10**
 21. **Figure 11**
 22. **Figure 12**
 23. **Figure 13**
 24. **Figure 14**
 25. **Figure 15**
 26. **Figure 16**
 27. **Figure 17**
 28. **Figure 18**
 29. **Figure 19**
 30. **Figure 20**
 31. **Figure 21**
 32. **Figure 22**
 33. **Figure 23**
 34. **Figure 24**
 35. **Figure 25**
 36. **Figure 26**
 37. **Figure 27**
 38. **Figure 28**
 39. **Figure 29**
 40. **Figure 30**
 41. **Figure 31**
 42. **Figure 32**
 43. **Figure 33**
 44. **Figure 34**
 45. **Figure 35**
 46. **Figure 36**
 47. **Figure 37**
 48. **Figure 38**
 49. **Figure 39**
 50. **Figure 40**
 51. **Figure 41**
 52. **Figure 42**
 53. **Figure 43**
 54. **Figure 44**
 55. **Figure 45**
 56. **Figure 46**
 57. **Figure 47**
 58. **Figure 48**
 59. **Figure 49**
 60. **Figure 50**
 61. **Figure 51**
 62. **Figure 52**
 63. **Figure 53**
 64. **Figure 54**
 65. **Figure 55**
 66. **Figure 56**
 67. **Figure 57**
 68. **Figure 58**
 69. **Figure 59**
 70. **Figure 60**
 71. **Figure 61**
 72. **Figure 62**
 73. **Figure 63**
 74. **Figure 64**
 75. **Figure 65**
 76. **Figure 66**
 77. **Figure 67**
 78. **Figure 68**
 79. **Figure 69**
 80. **Figure 70**
 81. **Figure 71**
 82. **Figure 72**
 83. **Figure 73**
 84. **Figure 74**
 85. **Figure 75**
 86. **Figure 76**
 87. **Figure 77**
 88. **Figure 78**
 89. **Figure 79**
 90. **Figure 80**
 91. **Figure 81**
 92. **Figure 82**
 93. **Figure 83**
 94. **Figure 84**
 95. **Figure 85**
 96. **Figure 86**
 97. **Figure 87**
 98. **Figure 88**
 99. **Figure 89**
 100. **Figure 90**
 101. **Figure 91**
 102. **Figure 92**
 103. **Figure 93**
 104. **Figure 94**
 105. **Figure 95**
 106. **Figure 96**
 107. **Figure 97**
 108. **Figure 98**
 109. **Figure 99**
 110. **Figure 100**
 111. **Figure 101**
 112. **Figure 102**
 113. **Figure 103**
 114. **Figure 104**
 115. **Figure 105**
 116. **Figure 106**
 117. **Figure 107**
 118. **Figure 108**
 119. **Figure 109**
 120. **Figure 110**
 121. **Figure 111**
 122. **Figure 112**
 123. **Figure 113**
 124. **Figure 114**
 125. **Figure 115**
 126. **Figure 116**
 127. **Figure 117**
 128. **Figure 118**
 129. **Figure 119**
 130. **Figure 120**
 131. **Figure 121**
 132. **Figure 122**
 133. **Figure 123**
 134. **Figure 124**
 135. **Figure 125**
 136. **Figure 126**
 137. **Figure 127**
 138. **Figure 128**
 139. **Figure 129**
 140. **Figure 130**
 141. **Figure 131**
 142. **Figure 132**
 143. **Figure 133**
 144. **Figure 134**
 145. **Figure 135**
 146. **Figure 136**
 147. **Figure 137**
 148. **Figure 138**
 149. **Figure 139**
 150. **Figure 140**
 151. **Figure 141**
 152. **Figure 142**
 153. **Figure 143**
 154. **Figure 144**
 155. **Figure 145**
 156. **Figure 146**
 157. **Figure 147**
 158. **Figure 148**
 159. **Figure 149**
 160. **Figure 150**
 161. **Figure 151**
 162. **Figure 152**
 163. **Figure 153**
 164. **Figure 154**
 165. **Figure 155**
 166. **Figure 156**
 167. **Figure 157**
 168. **Figure 158**
 169. **Figure 159**
 170. **Figure 160**
 171. **Figure 161**
 172. **Figure 162**
 173. **Figure 163**
 174. **Figure 164**
 175. **Figure 165**
 176. **Figure 166**
 177. **Figure 167**
 178. **Figure 168**
 179. **Figure 169**
 180. **Figure 170**
 181. **Figure 171**
 182. **Figure 172**
 183. **Figure 173**
 184. **Figure 174**
 185. **Figure 175**
 186. **Figure 176**
 187. **Figure 177**
 188. **Figure 178**
 189. **Figure 179**
 190. **Figure 180**
 191. **Figure 181**
 192. **Figure 182**
 193. **Figure 183**
 194. **Figure 184**
 195. **Figure 185**
 196. **Figure 186**
 197. **Figure 187**
 198. **Figure 188**
 199. **Figure 189**
 200. **Figure 190**
 201. **Figure 191**
 202. **Figure 192**
 203. **Figure 193**
 204. **Figure 194**
 205. **Figure 195**
 206. **Figure 196**
 207. **Figure 197**
 208. **Figure 198**
 209. **Figure 199**
 210. **Figure 200**
 211. **Figure 201**
 212. **Figure 202**
 213. **Figure 203**
 214. **Figure 204**
 215. **Figure 205**
 216. **Figure 206**
 217. **Figure 207**
 218

Commissioner for Patents
September 29, 2000
Page 2

the application consisting of:

- a. A specification containing:
 - i. 74 pages of description prior to the claims;
 - ii. 7 pages of claims (claims 1-41);
 - iii. 1 page abstract;
 - b. Eight (8) sheets of drawings (Figures 1; 2A-2C; 3-5; 6A-6B; 7A-7B and 8); and
 - c. A Declaration executed by the inventors (12 sheets);
4. Authorization To Treat a Reply As Incorporating An Extension Of Time Under 37 C.F.R. § 1.136(a)(3) (in duplicate);
 5. Recordation Form Cover Sheet (Form PTO-1595);
 6. An Assignment to The General Hospital Corporation, recordation of which is hereby respectfully requested;
 7. A Preliminary Amendment and Submission of Sequence Listing;
 8. A paper copy of the Sequence Listing;
 9. The Sequence Listing in computer readable form (3½" diskette in ASCII);
 10. Letter to PTO Draftsman: Submission of Formal Drawings;
 11. Thirteen (13) sheets of Formal Drawings (Figures 1A-1N; 2A-2C; 3-5; 6A-6B; 7A-7B and 8);
 12. Two (2) return postcards; and
 13. Our check No. 28944 for \$2,946.00 to cover:

\$ 690.00	Basic filing fee (37 C.F.R. § 1.16(a));
390.00	Independent claims in excess of three (37 C.F.R. § 1.16(b));
1,566.00	Claims in excess of twenty (37 C.F.R. § 1.16(c));
260.00	Multiple dependent claim (37 C.F.R. § 1.16(d)); and
40.00	Assignment recordation fee (37 C.F.R. § 1.21(h)).

006260-02024950

Commissioner for Patents

September 29, 2000

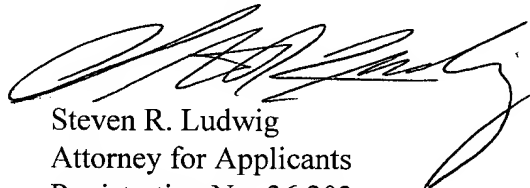
Page 3

In accordance with 37 C.F.R. § 1.821(f), the paper copy of the sequence listing and the computer readable copy of the sequence listing submitted herewith in the above application are the same.

It is respectfully requested that, of the two attached postcards, one be stamped with the filing date of these documents and returned to our courier, and the other, prepaid postcard, be stamped with the filing date and unofficial application number and returned as soon as possible. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


Steven R. Ludwig
Attorney for Applicants
Registration No. 36,203

SRL/TBB/dab

P:\USERS\DENISEB\0609\4822appcov

Enclosures

006260-02027960

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gardella *et al.*

Appl. No. (To be assigned)

Filed: (Herewith)

For: **Polypeptide Derivatives of
Parathyroid Hormone (PTH)**

Art Unit: (To be assigned)

Examiner: (To be assigned)

Atty. Docket: 0609.4820002/SRL/TBB



**Authorization To Treat A Reply As Incorporating An Extension Of Time
Under 37 C.F.R. § 1.136(a)(3)**

Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Sir:

The U.S. Patent and Trademark Office is hereby authorized to treat any concurrent or future reply that requires a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. The U.S. Patent and Trademark Office is hereby authorized to charge all required extension of time fees to our Deposit Account No. 19-0036, if such fees are not otherwise provided for in such reply. A duplicate copy of this authorization is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Steven R. Ludwig
Attorney for Applicants
Registration No. 36,203

Date: September 29, 2000

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JCS11 U.S. PTO
09/672020
09/29/00

In re application of:

Gardella *et al.*

Appl. No. (To be assigned)

Filed: (Herewith)

For: **Polypeptide Derivatives of
Parathyroid Hormone (PTH)**

Art Unit: (To be assigned)

Examiner: (To be assigned)

Atty. Docket: 0609.4820002/SRL/TBB

Letter to PTO Draftsman: Submission of Formal Drawings

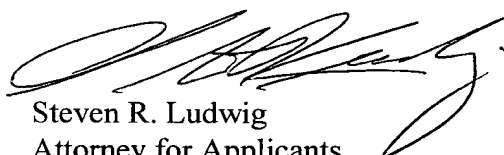
Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Sir:

Submitted herewith are thirteen (13) sheets of formal drawings with Figures 1A-1N; 2A-2C; 3-5; 6A-6B; 7A-7B and 8, corresponding to the informal drawings submitted with the above-captioned application. Acknowledgment of the receipt, approval, and entry of these formal drawings into this application is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


Steven R. Ludwig
Attorney for Applicants
Registration No. 36,203

Date: September 29, 2000

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600